

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act and this regulation is a prohibited act under section 301 of the Federal Food, Drug, and Cosmetic Act.

[80 FR 56144, Sept. 17, 2015]

COMPLIANCE DATES

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2006, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

[69 FR 71651, Dec. 9, 2004, as amended at 70 FR 8727, Feb. 23, 2005]

Subpart K—Administrative Detention of Food for Human or Animal Consumption

SOURCE: 69 FR 31701, June 4, 2004, unless otherwise noted.

GENERAL PROVISIONS

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded.

[76 FR 25541, May 5, 2011]

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not